SUMMARY OF EXPRESS TERMS

This rule establishes mental health and substance use disorder parity compliance program requirements to ensure that managed care organizations (MCOs) are providing coverage for benefits for the treatment of mental health and substance use disorder that is comparable to other health benefits provided by the MCO, as required under both state and federal law. The rule requires that such programs establish corporate governance for parity compliance, identify discrepancies in coverage of services for the treatment of mental health conditions and substance use disorder, provide mental health and substance use disorder training and education for employees and agents, and ensure appropriate identification and remediation of improper practices. Pursuant to the rule, MCOs are required to provide written notification to affected enrollees and the Commissioner regarding any identified improper practice. Failure to remediate improper practices under the rule may result in a civil penalty that would be deposited in a fund established pursuant to section 99-hh of the State Finance Law.

Pursuant to the authority vested in the Commissioner of Health by section 4403 of the Public Health Law, Part 98 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended by adding a new Subpart 98-4, to be effective 90 days after publication of the Notice of Adoption in the State Register, to read as follows:

A new Subpart 98-4 is added:

Section 98-4.1 Purpose

Section 98-4.2 Applicability

Section 98-4.3 Definitions

Section 98-4.4 Mental health and substance use disorder parity compliance program.

98-4.1 Purpose

The purpose of this Subpart is to establish mental health and substance use disorder parity compliance program requirements to ensure that managed care organizations (MCOs) are providing coverage for benefits for the treatment of mental health and substance use disorder that is comparable to other health benefits provided by the MCO, as required under both state and federal law. This Subpart requires that such compliance programs establish corporate governance for parity compliance, identify discrepancies in coverage of services for the treatment of mental health conditions and substance use disorder, and ensure appropriate identification and remediation of improper practices.

98-4.2 Applicability

This Subpart shall apply to all MCOs offering coverage that are subject to the mental health and substance use disorder requirements under Insurance Law § 4303 and Public Health Law § 4406.

98-4.3 Definitions. For the purposes of this Subpart, the following definitions shall apply:

- (a) *Benefit classification* means the following classifications of medical and surgical benefits and mental health and substance use disorder benefits for purposes of complying with the MHPAEA: inpatient in-network, inpatient out-of-network, outpatient in-network, outpatient out-of-network, emergency care and prescription drugs. The outpatient classification includes any subclassification of office visits.
- (b) *Comparative analysis* means an analysis of the nonquantitative treatment limitations imposed on mental health or substance use disorder benefits to determine if such limitations are comparable to and applied no more stringently, both as written and in operation, than nonquantitative treatment limitations imposed on medical or surgical benefits within the same benefit classification. Comparative analysis includes the documented identification and assessment of the factors, processes, strategies, and evidentiary standards the MCO relied upon to determine the applicability and design of a nonquantitative treatment limitation and the processes and strategies the MCO used in operationalizing a nonquantitative treatment limitation to illustrate MCO compliance with MHPAEA.

- (c) *Compliance program* means a mental health and substance use disorder parity compliance program.
- (d) *Financial requirements* means deductibles, copayments, coinsurance, and out-of-pocket maximums.
- (e) *Latency period* means the period of time that must elapse between the time at which a dose of drug is applied to a biologic system and the time at which a specified pharmacologic effect is produced.
- (f) *MHPAEA* means the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008, codified at 29 U.S.C. section 1185a, and its implementing regulations and sub-regulatory guidance.
- (g) Nonquantitative treatment limitation means a qualitative limit affecting the scope or duration of benefits such as medical management standards limiting or excluding benefits based on medical necessity, or based on whether the treatment is experimental or investigational; formulary design for prescription drugs; network tier design; standards for provider admission to participate in a network, including reimbursement rates; methods for determining usual, customary, and reasonable charges; fail-first or step therapy protocols; exclusions based on failure to complete a course of treatment; and restrictions based on geographic location, facility type, provider specialty, and other criteria that limit the scope or duration of benefits.

- (h) *Provider* means a physician, health care professional, or facility licensed, registered, certified, or otherwise authorized or accredited as required by state law.
- (i) Quantitative treatment limitation means a numerical limit affecting the scope or duration of benefits.
- 98-4.4. Mental health and substance use disorder parity compliance program.
- (a) Every MCO shall adopt and implement a compliance program that shall include at a minimum:
 - (1) designation of an appropriately experienced individual who shall:
 - (i) be responsible for assessing, monitoring, and managing parity compliance;
 - (ii) report directly to the MCO's chief executive officer or other senior manager; and
 - (iii) report no less than annually to the MCO's board of directors or other governing body, or the appropriate committee thereof, on the activities of the compliance program;
- (2) written policies and procedures that implement the compliance program, and that describe how the MCO's parity compliance is assessed, monitored, and managed, including:
 - a system for assigning each benefit to the defined benefit classifications as required by MHPAEA;
 - (ii) methodologies for the identification and testing of all financial requirements and quantitative treatment limitations; and

- (iii) methodologies for the identification and testing, including a comparative analysis, of all non-quantitative treatment limitations that are imposed on mental health or substance use disorder benefits;
- (3) methodologies for the identification and remediation of improper practices, as described in paragraph (1) of subdivision (b) of this section;
 - (4) a system for the ongoing assessment of parity compliance, which shall include:
 - review of a statistically valid sample of preauthorization, concurrent, and retrospective review denials for mental health and substance use disorder benefits to ensure such determinations were consistent with the clinical review criteria approved by the commissioner of mental health or designated by the commissioner of addiction services and supports, in consultation with the superintendent of financial services and the commissioner, and that such criteria have been applied comparably to and no more stringently than criteria applied to medical or surgical benefits;
 - (ii) review of the comparability of coverage within each benefit classification for mental health and substance use disorder benefits to ensure that coverage for a comparable continuum of services is available for mental health and substance use disorder benefits as is available for medical or surgical benefits, including residential and outpatient rehabilitation services;
 - (iii) review of the percentage of services provided by out-of-network providers for mental health and substance use disorder benefits where no in-network provider

was available, compared to the percentage of services provided by out-ofnetwork providers for medical and surgical benefits where no in-network
provider was available, to ensure that the processes and strategies for the
recruitment and retention of mental health and substance use disorder providers
are effective in reducing disparities in out-of-network use and to ensure that there
is an adequate network of mental health and substance use disorder providers to
provide services on an in-network basis;

- (iv) review of provider credentialing policies and procedures to ensure that the documentation and qualifications required for credentialing mental health and substance use disorder providers are comparable to and applied no more stringently than the documentation and qualifications required for credentialing medical or surgical providers and to ensure that there is an adequate network of mental health and substance use disorder providers to provide services on an innetwork basis:
- review of the average length of time to negotiate provider agreements and negotiated reimbursement rates with network providers and methods for the determination of usual, customary and reasonable charges, to ensure that reimbursement rates for mental health and substance use disorder benefits are established using standards that are comparable to and applied no more stringently than the standards used for medical or surgical benefits and to ensure that there is an adequate network of mental health and substance use disorder providers to provide services on an in-network basis;

- (vi) review of MCO policies for the automatic or systematic lowering, non-payment or application of a particular coding for mental health and substance use disorder benefits to ensure that they are comparable to and applied no more than stringently than MCO policies for the automatic or systematic lowering, nonpayment or application of a particular coding for medical or surgical benefits;
- (vii) review of all mental health and substance use disorder medications subject to nonquantitative treatment limitations, including step-therapy protocols or other preauthorization requirements, to ensure that the factors such as cost and latency periods, processes, strategies, and evidentiary standards the insurer relied upon to determine whether to apply the nonquantitative treatment limitation were comparable to and applied no more stringently than the factors, processes, strategies, and evidentiary standards the insurer relied upon to determine whether to apply nonquantitative treatment limitations, including step therapy or other preauthorization requirements, to medications to treat medical or surgical conditions;
- (viii) review of any fail-first requirements applicable to mental health or substance use disorder benefits to ensure that they are comparable to and applied no more stringently than any fail-first requirements applicable to medical or surgical benefits; and
- (ix) review of any restrictions based on geographic location, facility type, provider specialty, or other criteria applicable to mental health or substance use disorder

benefits to ensure that any such restriction is comparable to, and applied no more stringently than, any restriction applicable to medical or surgical benefits;

- (5) a process for the actuarial certification in compliance with actuarial standards of practice, of the data used for, and the outcome of, the analyses of the financial requirements and quantitative treatment limitations applicable to mental health and substance use disorder benefits to ensure that they are no more restrictive than the predominant financial requirements and quantitative treatment limitations applied to substantially all the medical and surgical benefits;
- (6) training and education on federal and state mental health and substance use disorder parity requirements for all employees, directors, or other governing body members, agents, and other representatives engaged in functions that are subject to federal or state mental health and substance use disorder parity requirements or involved in analysis as a part of the compliance program; provided that such training shall occur at least annually and shall be made a part of the orientation for such new employees, directors, or other governing body members, agents, and other representatives;
- (7) the methods by which employees, directors or other governing body members, agents, and other representatives may report parity compliance issues to the individual responsible for compliance, as described in subdivision (a) of this section; provided that such methods shall include a method for anonymous and confidential reporting of potential compliance issues as they are identified; and

- (8) a policy of non-intimidation and non-retaliation for good faith participation in the compliance program, including reporting and investigating potential issues and reporting to appropriate officials as provided in Labor Law §§ 740 and 741.
- (b) Improper practices prohibited.
- (1) The following shall be considered improper practices related to mental health and substance use disorder benefits:
 - (i) implementing a utilization review policy that uses standards to determine the level of documentation required for utilization review of mental health or substance use disorder benefits that are not comparable to or are applied more stringently than the standards used to determine the level of documentation required for the utilization review of medical or surgical benefits, including the submission of medical records, treatment plans, or evidence of patient involvement or motivation in care or patient response to treatment;
 - (ii) requiring preauthorization, concurrent, or retrospective utilization review for a higher percentage of mental health or substance use disorder benefits in the absence of defined clinical or quality triggers, as compared to medical or surgical benefits;
 - (iii) implementing a methodology for developing and applying provider reimbursement rates for mental health or substance use disorder benefits that is not comparable to or is applied more stringently than the methodology for

- developing and applying provider reimbursement rates for medical or surgical benefits; and
- (iv) implementing claim edits or system configurations that provide for higher rates of approval through auto-adjudication for claims for inpatient medical or surgical benefits than for inpatient mental health or substance use disorder benefits.
- (2) An MCO shall monitor for and detect improper practices as described in paragraph one of this subdivision and remediate or develop a plan to remediate any improper practices as soon as practicable, but in no event later than 60 days after discovery.
- (3) An MCO shall provide written notification to affected enrollees and the Commissioner and conspicuously post on the MCO's website a notice regarding any identified improper practice described in paragraph (1) of this subdivision, including a description of the MCO's efforts to remediate the improper practice or its plan for remediation, within 60 days of discovery of the improper practice.
- (c) An MCO shall be responsible for and coordinate parity compliance monitoring activities with any agents and other representatives providing benefit management services or performing utilization review activities on behalf of the MCO.
- (d) Annual certification.
- (1) By December 31, 2021 and annually thereafter, each MCO shall electronically submit a written certification to the commissioner that the MCO satisfactorily meets the requirements of this subpart.

- (2) Such certification shall be in a form prescribed by the Commissioner and signed by the MCO's chief executive officer or the individual responsible for assessing, monitoring, and managing the compliance program, attesting to the best of such individual's knowledge and belief that the information contained therein is true and that a copy of the certification has been provided to the MCO's board of directors or other governing body, or the appropriate committee thereof.
- (e) Exemptions from electronic filing and submission requirements.
- (1) An MCO required to make an electronic filing or a submission pursuant to this subpart may apply to the Commissioner for an exemption from the requirement that the filing or submission be electronic by submitting a written request to the Commissioner for approval at least 30 days before the MCO is required to submit to the Commissioner the particular filing or submission that is the subject of the request.
 - (2) The request for an exemption shall:
 - (i) set forth the MCO's NAIC number, if applicable;
- (ii) identify the specific filing or submission for which the MCO is applying for the exemption;
- (iii) specify whether the MCO is making the request for an exemption based upon undue hardship, impracticability, or good cause, and set forth a detailed explanation as to the reason that the Commissioner should approve the request; and
- (iv) specify whether the request for an exemption extends to future filings or submissions, in addition to the specific filing or submission identified in paragraph (2) of this subdivision.

- (3) The MCO requesting an exemption shall submit, upon the Commissioner's request, any additional information necessary for the Commissioner to evaluate the MCO's request for an exemption.
- (4) The MCO shall be exempt from the electronic filing or submission requirement upon the Commissioner's written determination so exempting the MCO, where the determination specifies the basis upon which the Commissioner is granting or denying the request and to which filings or submissions the exemption applies.
- (5) If the Commissioner approves an MCO's request for an exemption from the electronic filing or submission requirement, then the MCO shall make a physical filing in a form acceptable to the Commissioner.

REGULATORY IMPACT STATEMENT

Statutory Authority:

Public Health Law (PHL) section 4403(2) states the Commissioner may adopt and amend rules and regulations to effectuate the purposes and provisions of Article 44, which governs the certification and operational requirements of managed care organizations (MCOs).

Legislative Objectives:

Insurance Law section 4303 and Public Health Law § 4406 subject MCOs to certain mental health treatment and substance use disorder parity requirements, in accordance with the federal Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (29 U.S.C. section 1185a). Chapter 58 of the Laws of 2020 added Public Health Law section 4414(2) which provides that penalties collected from MCOs for violations of Insurance Law section 4303 shall be deposited in a fund established pursuant to State Finance Law section 99-hh.

This proposed rule accords with the public policy objectives that the Legislature sought to advance in Chapter 58 by establishing compliance program requirements to ensure that MCOs certified pursuant to Article 44 of the Public Health Law are providing comparable coverage for benefits to treat mental health and substance use disorder as required under both state and federal law. The proposed rule also requires that such compliance programs establish corporate governance for parity compliance, identify discrepancies in coverage of services for the treatment of mental health conditions and substance use disorder, and ensure appropriate identification and remediation of improper practices.

Needs and Benefits:

The Department finds that access to treatment for mental health and substance use disorder services is critical to abate the opioid and suicide epidemics affecting families throughout the state. Further, in accordance with state and federal law, MCOs are required to ensure they are offering comparable coverage and benefits for the treatment of mental health conditions and substance use disorder as they are for medical and surgical conditions. It is therefore in the public interest that MCOs implement compliance programs to effectuate and monitor parity compliance.

COSTS:

Costs to the Regulated Entities:

MCOs may incur additional costs to comply with the rule. The additional costs may include compliance costs associated with establishing and maintaining a compliance program. Specifically, MCOs will be responsible for creating written policies and procedures that implement the program and describe how the MCO's parity compliance is assessed, monitored and maintained, including methodologies for the identification and testing of all financial requirements and both quantitative and non-quantitative treatment limitations. Further the compliance program requires the identification and remediation of improper practices as well as training and education for all employees and other agents engaged in functions that are subject to state mental health and substance use disorder parity requirements. Any costs associated with the parity compliance program are expected to be minimal because prior to this proposed rule, MCOs were required to have undertaken significant measures to ensure compliance with state and federal mental health and substance use disorder parity requirements.

Costs to Local Governments:

The proposed changes are not expected to impose any costs upon local governments.

Costs to the Department of Health:

This proposed rule may impose compliance costs on the Department because the Department will be required to monitor whether MCOs are maintaining a compliance program that meets the requirements of this rule, identify improper MCO practices, and assess whether MCOs are remediating improper practice in a timely manner.

Local Government Mandates:

The proposed rule does not impose any program, service, duty or responsibility on any county, city, town, village, school district, fire district or other special district.

Paperwork:

Consistent with the statutory provisions, the proposed rule will require that MCOs establish corporate governance for parity compliance, identify discrepancies in coverage of services for the treatment of mental health conditions and substance use disorder, ensure appropriate identification and remediation of improper practices, and certify annually that the requirements of the regulations have been satisfactorily met. MCOs will incur additional paperwork to comply with this rule because they will need to provide written policies and procedures that implement the compliance program within their organization. MCOs will also be required to provide written notification to affected enrollees regarding identified improper practices.

Duplication:

This rule does not duplicate, overlap, or conflict with any existing state or federal rules or other legal requirements.

Alternatives:

There are no significant alternatives to consider except to not issue this rule. The establishment of a compliance program is necessary given the addition of Public Health Law section 4414(2) and State Finance Law section 99-hh, as created by Chapter 58 of the Laws of 2020. Section 4414(2) states that penalties collected for mental health and substance use disorder parity violations shall be deposited in the compliance fund, as created under 99-hh, but it fails to define what a compliance program is. The proposed rule provides detailed requirements and minimum standards for MCOs' mental health and substance use disorder parity compliance programs. Because of the importance of these provisions in helping ensure access to mental health and substance use disorder services, the alternative of not issuing this rule was rejected,

Federal Standards:

The rule does not exceed any minimum standards of the federal government for the same or similar subject areas.

Compliance Schedule:

The regulations will take effect 90 days after publication of the Notice of Adoption in the State Register.

Contact Person: Katherine Ceroalo

New York State Department of Health

Bureau of Program Counsel, Regulatory Affairs Unit

Corning Tower Building, Room 2438

Empire State Plaza

Albany, New York 12237

(518) 473-7488

(518) 473-2019 (FAX)

REGSQNA@health.ny.gov

REGULATORY FLEXIBILITY ANALYSIS FOR SMALL BUSINESSES AND LOCAL GOVERNMENTS

Effect of Rule:

This rule affects managed care organizations certified pursuant to Article 44 of the Public Health Law ("MCOs"). Chapter 58 of the Laws of 2020 added Public Health Law § 4414(2) which provides that penalties collected for violations of Insurance Law sections 4303 related to mental health and substance use disorder parity compliance shall be deposited in a fund established pursuant to State Finance Law § 99-hh. This rule establishes mental health and substance use disorder parity compliance program ("compliance program") requirements to ensure that MCOs are providing comparable coverage for benefits for the treatment of mental health and substance use disorder that is comparable to other health benefits provided by the MCO, as required under both state and federal law. This rule further requires that such compliance programs establish corporate governance for parity compliance, identify discrepancies in coverage of services for the treatment of mental health conditions and substance use disorder, and ensure appropriate identification and remediation of improper practices.

This rule does not affect local governments.

Compliance Requirements:

No local government will have to undertake any reporting, recordkeeping, or other affirmative acts to comply with this rule because the rule does not apply to any local government.

An MCO who is a small business will be subject to reporting, recordkeeping, or other compliance requirements as required by a compliance program. Any additional compliance requirements should be minimal because current state and federal law already requires MCOs who are small businesses to comply with mental health parity and substance use disorder requirements.

Professional Services:

No local government will need professional services to comply with this rule because the rule does not apply to any local government. No MCO that is a small business affected by this rule should need to retain professional services, such as lawyers or auditors, to comply with this rule.

Compliance Costs:

Costs to Regulated Parties:

MCOs who are small businesses may incur additional costs to comply with this rule. The additional costs may include costs associated with the training and education of employees, members of the board of directors, other governing body members, agents, and other contracted entities engaged in functions that are subject to state mental health and substance use disorder parity requirements. In addition, MCOs will be required to provide written notification to affected enrollees regarding identified improper practices, However, any additional costs should be minimal because state and federal law already require MCOs who are small businesses to comply with mental health parity and substance use disorder requirements.

Costs to State Government and Local Government:

State government will be responsible for enforcement. Any costs for enforcement will be managed within existing resources. There will be no costs to local governments.

Economic and Technological Feasibility:

The rule does not apply to any local government; therefore, no local government should experience any economic or technological impact as a result of the rule.

MCOs who are small businesses should not incur any economic or technological impact as a result of the rule.

Minimizing Adverse Impact:

There will not be an adverse impact on any local government because the rule does not apply to any local government. This rule should not have an adverse impact on an MCO who is a small business because it uniformly affects all MCOs who are subject to the rule.

Small Business and Local Government Participation:

The Department will comply with SAPA section 202-b(6) by providing MCO associations with a summary of the rule prior to the public comment period, publishing the proposed amendment in the State Register and posting the proposed amendment on its website.

RURAL AREA FLEXIBILITY ANALYSIS

Types and estimated numbers of rural areas:

Managed care organizations certified pursuant to Public Health Law article 44 ("MCOs") affected by this rule operate in every county in this state, including rural areas as defined by State Administrative Procedure Act section 102(10).

Reporting, recordkeeping and other compliance requirements; and professional services:

MCOs, including MCOs in rural areas, may be subject to additional reporting, recordkeeping, or other compliance requirements as the implementation of a mental health and substance use disorder parity compliance program ("compliance program") requires a record of ongoing assessment and monitoring of parity compliance including methodologies for the identification and testing of all financial requirements and both quantitative and non-quantitative treatment limitations. However, these additional compliance requirements are expected to be minimal because current state and federal law already requires MCOs to comply with mental health and substance use disorder parity requirements.

An MCO in a rural area should not need to retain professional services, such as lawyers or auditors, to comply with this rule.

Costs:

MCOs may incur additional costs to comply with the rule. The additional costs may include costs associated with the aforementioned reporting, recordkeeping, and other compliance costs. Further the program requires training and education for all employees, members of the

board of directors, other governing body members, agents, and other contracted entities engaged in functions that are subject to state mental health and substance use disorder parity requirements. Any costs associated with the compliance program should be minimal because prior to this proposed rule, MCOs would have undertaken significant measures to ensure compliance with state and federal mental health and substance use disorder parity requirements.

Minimizing adverse impact:

This rule uniformly affects MCOs that are located in both rural and non-rural areas of New York State. This rule should not have an adverse impact on rural areas.

Rural area participation:

MCOs, including MCOs in rural areas, will have an opportunity to participate in the rule-making process by submitting comments after the proposed rule is published in the State Register and on the Department of Health's website.

STATEMENT IN LIEU OF

JOB IMPACT STATEMENT

No Job Impact Statement is required pursuant to section 201-a(2)(a) of the State Administrative Procedure Act. No adverse impact on jobs and/or employment opportunities is expected as a result of these proposed regulations.

SUMMARY OF THE ASSESSMENT OF PUBLIC COMMENTS

In response to the publication of the proposed rule in the New York State Register, the New York State Department of Health (Department) received comments from associations that represent managed care organizations (MCOs), associations that represent healthcare providers, and advocacy organizations that provide or promote mental health and substance use disorder health care services.

Interested parties submitted a number of comments, including comments that state that: the Department should amend the regulation to reference the Mental Health and Substance Use Disorder Parity Report Act (Parity Report Act) and explicitly mandate compliance with the Parity Report Act; the regulation should provide information on the interplay between the data submission requirements of the Parity Report Act and the Mental Health and Substance Use Disorder Parity Compliance Program (Parity Compliance Program); the regulation should require that the Department publish and make information regarding an MCO's remediation efforts available on the Department's website; the regulation should require an MCO to publish its compliance activities on its public facing website; the regulation should require that an MCO make available to the public its annual compliance certification by posting it on the MCO's public facing website; the regulation should state that civil penalties may be imposed on the MCOs that engage in improper practices; section 98-4.4(a)(4)(iii), (iv), and (v) of the regulation should contain the phrase "and to ensure there is an adequate network of mental health and substance use disorder providers to provide services on an in-network basis," consistent with the language in the regulation proposed by the Department of Health; the requirement for MCOs to provide training and education to its employees should specify that the training and education

must relate to the requirements of federal and state mental health and substance use disorder parity laws and regulations; the regulation should include additional instances of improper practices; the Department should revise section 98-4.4(b)(1)(i) of the regulation to remove the reference to "different" standards and replace it with a reference to standards that are "not comparable to or applied more stringently than"; the Department should delete the public posting requirement contained in section 98-4.4(b)(3) of the regulation; the Department should clarify what constitutes "appropriately experienced" to ensure that the Parity Compliance Program is appropriately administered and amend the regulation to specify that "appropriately experienced" means "with a background or training in Parity Act compliance"; the Department should require MCOs to make specific disclosures to enrollees about their parity compliance efforts, including information about the parity compliance officer and the officer's role in providing required disclosures and securing parity compliant benefits and require MCOs to provide annual reports of compliance activities, such as comparative reviews, to plan enrollees; the date by which MCOs must certify compliance is both too far in the future and not far enough; the 60-day time period after discovery to remediate and report improper practices is both too long and too short; and the Department should convene a work group to provide input into the drafting of the standard certification form or should allow stakeholders to review and comment on the form when developed.

The Department amended the rule to clarify certain language. The Department did not make any substantive changes to the rule in light of the comments. The Department has posted on its website a complete assessment of the public comments that the Department received regarding the rule.

ASSESSMENT OF PUBLIC COMMENTS

The New York State Department of Health (Department) received comments from associations that represent managed care organizations (MCOs), associations that represent healthcare providers, and advocacy organizations that provide or promote mental health and substance use disorder health care services. Many of the comments supported the regulation. However, some commenters requested changes to, or clarification of, the regulation.

<u>Comment</u>: One commenter suggested that the regulation be amended to make specific reference to the Mental Health and Substance Use Disorder Parity Report Act (Parity Report Act) and explicitly mandate compliance with the Act. In addition, the commenter requested information on the interplay between the data submission requirements of the Parity Report Act and the regulation's Mental Health and Substance Use Disorder Parity Compliance Program (Parity Compliance Program).

Response: While the Parity Compliance Program and the Parity Report Act both relate to parity compliance, the two stem from separate regulatory and legal authority and have somewhat different objectives. There is no need for the regulation to reference the Parity Report Act or mandate compliance with that Act, the requirements of which are already contained in Insurance Law §343. The Department did not make any changes in response to this comment.

<u>Comment</u>: One commenter expressed strong support for the requirement that MCOs conspicuously post on their websites any improper practices and issues for remediation within 60 days of discovery but suggested that the regulation also require that the Department publish and make the same information available on the Department's website to ensure that this information is widely available to the public.

Response: The proposed regulation, as written, would not prohibit the Department from publishing this information on its website and the Department would be willing to consider this option in the future. However, the Department does not wish to include this as a requirement in the regulation as its website policies and content are subject to change. The Department did not make any changes in response to this comment.

<u>Comment</u>: One commenter requested that the Department amend the regulation to mandate that in addition to reporting its compliance activities to its board of directors, the MCO publish its compliance activities on its public-facing website.

Response: The proposed regulation currently requires an MCO to publish any identified improper practices and its remediation efforts on its website. While an additional requirement to publish its compliance activities on its website would increase the burden on the MCO, it is unclear what the added benefit to the enrollee would be. As a result, the Department does not believe the additional burden on the MCO is justified in this instance. The Department did not make any changes to the regulation in response to this comment.

<u>Comment</u>: One commenter suggested that the annual certification of an MCO's compliance on a form prescribed by the Department be made available to the public by means of posting it on the MCO's public facing website.

Response: The proposed regulation requires that each MCO submit an annual written certification to the Department that the MCO satisfactorily meets the requirements of the regulation. The Department will maintain records of the certifications and will follow up with an MCO should the MCO fail to provide a timely certification. The Department is unsure how enrollees or the Department would benefit by requiring an MCO to post its annual certification

on its website. The Department did not make any changes to the regulation in response to this comment.

<u>Comment</u>: Section 98-4.4(a)(6) of the proposed regulation currently requires "training and education for all employees...." A commenter suggested that the Department amend this language to clarify that the training and education is "on the requirements of federal and state mental health and substance use disorder parity laws".

Response: The Department has added language to the regulation to clarify that the training and education referred to is on federal and state mental health and substance use disorder parity requirements.

Comment: Two commenters suggested that the Department amend section 98-4.4(b)(1) of the proposed regulation to include additional instances of improper practices, such as implementing automatic or systemic non-payment or down-coding of Current Procedural Terminology codes used for the care and treatment of mental health and substance use disorder and failure to provide comparable reimbursement for evaluation and management claims submitted by psychiatrists when the underlying service is provided in the course of treatment of a mental illness or substance use disorder.

Response: The Department reviewed the suggested amendments but does not believe it is necessary to include additional improper practices in the proposed regulation. All practices by MCOs related to either quantitative or nonquantitative treatment limitations on mental health and substance use disorder benefits must be consistent with the federal Mental Health Parity and Addiction Equity Act (MHPAEA), regardless of whether they are specifically listed in the regulation as an improper practice. The Department did not make any changes in response to this comment.

<u>Comment</u>: One commenter recommended that the Department adhere to the practices described in the U.S. Department of Labor's Employee Benefits Security Administration MHPAEA Self-Compliance Tool (DOL Self-Compliance Tool).

Response: The Department reviewed the referenced DOL Self-Compliance Tool, including the proposed MHPAEA Compliance Plan recommendations, and concluded that, although the proposed regulation provides more detail than the DOL recommendations for compliance plans, it is consistent with the objectives of the DOL recommendations. The Department did not make any changes in response to this comment.

<u>Comment</u>: One commenter requested that the Department revise the definition of "comparative analysis" in the proposed regulation to enhance clarity and to ensure fidelity to the MHPAEA standards.

Response: The Department reviewed the definition of "comparative analysis" in the proposed regulation and determined that the definition is clear and not inconsistent with the MHPAEA standards. The Department did not make any changes in response to this comment.

Comment: With respect to section 98-4.4(a)(4) of the regulation, one commenter stated that the items that the regulation requires MCOs to review in conjunction with monitoring ongoing compliance over-emphasize results, rather than focusing on methodologies, evidentiary standards, factors, and policies and procedures used by MCOs in establishing and applying nonquantitative treatment limitations (NQTLs). The commenter requested that the Department revise paragraph (4) to require that MCOs have "a system for the ongoing assessment of parity compliance, which may include" review of the listed items.

Response: The items that the regulation requires MCOs to review in conjunction with monitoring ongoing compliance are intended to assist MCOs in determining whether the

methodologies, evidentiary standards, factors, and policies and procedures used in establishing and applying NQTLs are MHPAEA compliant. They are not intended to demonstrate a MHPAEA violation based solely on the results of the review of those items. Further, the list of items is not exhaustive, and MCOs may review items not specifically enumerated in the proposed regulation. The Department did not make any changes in response to this comment.

Comment: One commenter requested that the Department revise section 98-4.4(b)(1)(i) of the regulation to remove reference to "different" standards and replace it with a reference to standards that are "not comparable to or applied more stringently than." The commenter states that the change is necessary because the use of "different" standards is permissible under the law, as long as the standards are comparable and applied no more stringently.

Response: Although the Department interprets the word "different" in this context to mean "not comparable to or applied more stringently than," we amended the regulation in accordance with the comment for clarity.

Comment: One commenter requested that the Department revise section 98-4.4(b)(1)(ii) of the regulation so that the improper practice is not dependent on whether an MCO engages in utilization review of mental health or substance use disorder benefits more than it does for medical or surgical benefits. The commenter states that the fact that a higher percentage of mental health and substance use disorder services are subject to utilization review than medical or surgical services is permissible under the law as long as the standards for imposing utilization review on both types of services are comparable and applied no more stringently.

Response: The proposed regulation recognizes that a higher percentage of utilization review for mental health or substance use disorder services does not result in an improper practice in and of itself. The proposed regulation specifically provides that it is only an improper

practice in the absence of defined clinical or quality triggers. Therefore, the Department did not make any changes in response to this comment.

Comment: One commenter requested that the Department delete section 98-4.4(b)(1)(iv) of the regulation because an auto adjudication process does not limit scope or duration of benefits and is not an NQTL. The commenter states that federal guidance suggests higher rates of approval through auto adjudication for claims for inpatient medical or surgical benefits than for inpatient mental health or substance use disorder benefits is a "red flag" but not necessarily a violation.

Response: The proposed regulation does not provide that the improper practice is necessarily a violation of MHPAEA. The Department is not precluded from finding that a practice that indicates a potential MHPAEA violation is an improper practice within the framework of the proposed regulation. The Department did not make any changes in response to this comment.

Comment: Two commenters suggested removal of the public posting requirement contained in section 98-4.4(b)(3) of the regulation because, according to the commenters: the requirement creates a perverse incentive for health plans to determine that an identified compliance risk does not in fact constitute an improper practice in order to avoid the notice requirement, since providing such notice puts beneficiaries and plaintiffs' attorneys on notice of their opportunity to sue the plan for non-compliance; the public display of violations is overly punitive given the vagueness and complexity of federal guidance on measures of NQTL compliance; it may violate due process as it requires self-reporting of violations publicly; often times, there are legitimate disagreements on NQTL compliance and any posting of noncompliance could lead to inappropriate public admonishments; and since such a notice would

likely be posted after the noncompliance has been remediated, any minimal public benefit it may provide will be substantially outweighed by the confusion it would cause.

Response: Rather than incentivizing an MCO to determine that a compliance risk is not an improper practice as argued in the comment, the Department believes that it will provide additional incentive for an MCO to ensure that they are in compliance with the regulation.

While NQTL compliance may be complex, the Department believes that the improper practices as described in the regulation are clear and will not be overly burdensome on MCOs to detect. The Department does not understand the due process argument as it is the MCO's own determination as to whether it has engaged in an improper practice as identified in the regulation. Therefore, the Department did not make any changes in response to this comment.

Comment: One commenter expressed strong support for the Department's proposal that each MCO designate an "appropriately experienced" person to manage parity compliance. However, two commenters recommended that the Department provide clarification on what constitutes "appropriately experienced" to ensure that the compliance program is appropriately administered. A commenter suggested that "appropriately experienced" be qualified with the language "with a background or training in Parity Act compliance."

Response: It is the responsibility of the MCO to determine whether an individual is appropriately experienced in this regard and is unsure of the benefit of qualifying this language. It is inferred that this individual should either be familiar with or have a background or training in parity compliance and it was not the intent of the proposed regulation to monitor or audit the credentials or qualifications of the chosen individual. The Department did not make any changes to the regulation in response to this comment.

Comment: One commenter requested that the Department amend the definition of "financial requirements" so that it does not present an exclusive list of financial requirements but only an illustrative list. The commenter also suggested that the definition of an "NQTL" remove the term "qualitative limit" and instead use the language "limitation on scope or duration of benefits that is not expressed numerically." Additionally, the commenter suggested that the Department should define "statistically valid sample" and "down-coding" because it is not clear what they mean.

Response: The regulation defines "financial requirement" as deductibles, copayments, coinsurance, and out-of-pocket maximums. The Department believes the current definition is clear and sufficiently captures all financial requirements. It is unclear what the commenter believes is not captured and why only an illustrative list is needed. With regard to the definition of NQTL, the Department believes the current language "qualitative limit affecting the scope or duration of benefits" has the same meaning as the suggested "limitation on scope or duration of benefits that is not expressed numerically" and prefers the current positive language as it provides clarity and describes what an NQTL is, "a qualitative limit affecting the scope or duration" versus the commenter's suggested negative language which explains what an NQTL is not, "limitation on scope or duration...not expressed numerically." The Department did not define "statistically valid sample" because the Department believes the word's meaning is sufficiently clear in the context in which it is presented. The meaning of down-coding will be clarified in 98-4.4(a)(4)(vi), consistent with language used in Public Health Law.

<u>Comment</u>: One commenter requested clarification as to why latency period is used as a factor for determining whether to apply an NQTL to medications in section 98-4.4(a)(4)(vii).

Response: The Department included latency period in section 98-4.4(a)(4)(vii) of the regulation because the Department recognizes that a drug's latency period is a factor that an MCO may consider in its decision to apply an NQTL to a prescription drug

<u>Comment</u>: Regarding the proposed regulation's annual certification requirement, one commenter suggested that the Department revise the proposed regulation to require MCOs to use a standardized form that sets forth instruction and definitions to ensure standardization across all MCOs and permit the Department to monitor for any irregularities and ensure appropriate remediation.

Response: Section 98-4.4(d)(2) of the regulation states in relevant part that "[s]uch certifications shall be in a form prescribed by the commissioner." As a result, all MCOs will use a standardized form and the Department did not make any changes to the regulation in response to this comment.

<u>Comment</u>: One commenter recommended requiring MCOs to make specific disclosures to plan enrollees about their parity compliance efforts, including information about the parity compliance officer and his or her role in providing required disclosures and securing parity compliant benefits. In addition, the commenter suggested that the regulation require MCOs to provide annual reports of compliance activities, including comparative reviews, to plan enrollees.

Response: The Department believes mental health and substance use disorder parity compliance is a complex matter that is best assessed and overseen by the Department and is unclear as to the benefit of requiring MCOs to disclose the details of their compliance efforts to plan enrollees. The Department did not make any changes to the regulation in response to this comment.

<u>Comment</u>: Section 98-4.4(b)(3) of the regulation requires MCOs to provide written notification to affected enrollees that includes a description of efforts to remediate the improper practice. One commenter suggested that the Department amend this section to address the details of remediation, including the re-adjudication of claims and restitution to adversely impacted enrollees who were harmed by the violation.

Response: The Department believes the language of section 98-4.4(b)(3) that references the disclosure of remediation efforts to enrollees applies to and implies the re-adjudication of claims and restitution, where applicable. For this reason, the Department did not make any changes to the regulation in response to this comment.

Comment: One commenter requested that the Department amend section 98-4.4(a)(4)(iii) of the regulation to clarify what the regulation means when it references no innetwork provider being "available", arguing that it could be read to mean that a provider is not available for an appointment in a specified amount of time, is not within a defined travel time or distance from the patient, or is not accepting new patients.

Response: The Department did not specify what is meant by the term "available" because it intended the term to apply broadly. As a result, "available" would include when a provider is not available for an appointment in a specified amount of time, is not within a defined travel time or distance from the patient or is not accepting new patients. Thus, the Department did not make any changes to the regulation in response to this comment.

<u>Comment</u>: One commenter suggested that the Department amend section 98-4.4(a)(4)(v) to clarify that the reviews required in this section are a review of the average length of time to negotiate provider agreements and a review of negotiated reimbursement rates and the methods

of determination of usual, customary and reasonable charges, as both are important reviews that will illustrate different potential parity violations.

Response: The Department believes this comment may have been submitted in error because these two reviews are already specified in section 98-4.4(a)(4)(v) of the regulation. Thus, the Department did not make any changes in response to this comment.

Comment: One commenter recommended that the Department amend section 98-4.4(a)(4)(vii) of the regulation, which references several NQTLs related to medications, to add tier placement to the list and add catch all language for any other utilization management requirements not expressed.

Response: The Department believes that the language in section 98-4.4(a)(4)(vii) clearly indicates that the list of NQTLs is not exclusive and only meant to be illustrative and therefore is unsure as to the benefit of naming additional limitations. The Department did not make any changes in response to this comment.

<u>Comment</u>: One commenter requested that the Department amend the definition of "comparative analysis" to include additional detail via a step-wise process as put forward in The Kennedy Forum, American Psychiatric Association, and Parity Implementation Coalition's Six-Step Compliance Guide or in the DOL Self-Compliance Tool.

Response: The regulation is not intended to prescribe a process or tool that every MCO must use. It provides flexibility to an MCO to choose a process or tool that works best for it, with the understanding that whatever process or tool the MCO chooses, the MCO must be able to demonstrate that it is in compliance with MHPAEA. The Department did not make any changes in response to this comment

Comment: The proposed regulation requires the designation of an individual who is responsible for assessing, monitoring, and managing parity compliance. One commenter urged that this individual be responsible for responding to enrollees and provider requests relating to potential parity problems and that this person be responsible for ensuring that required disclosures, including medical necessity criteria both for mental health and substance use disorder and medical/surgical benefits and parity analyses, are made to providers and enrollees pursuant to state and federal law.

Response: The regulation requires that the Parity Compliance Program include the designation of an appropriately experienced individual who is responsible for assessing, monitoring and managing parity compliance. Within that framework, the proposed regulation is intended to provide MCOs with some flexibility as to how they comply with state and federal parity laws. The Department did not make any changes in response to this comment.

Comment: One commenter suggested that the Department amend section 98-4.4(a)(6) of the regulation to make explicit that "functions that are subject to federal or state mental health and substance use disorder parity requirements or involved in analysis as a part of the compliance program" include functions relating to medical or surgical benefits, as MHPAEA is a comparative law that is equally dependent on MCOs' medical or surgical benefits. Related to this, the commenter suggested that the Department revise the proposed regulation to include a requirement that an MCO must analyze any changes to either mental health and substance use disorder or medical or surgical benefits before implementing them.

Response: While it is true that MHPAEA is a comparative law, the training referred to in the proposed regulation is intended for those individuals whose functions are related to parity compliance, not to all employees who are involved with medical or surgical benefits.

Additionally, mental health and substance use disorder benefits must be provided in compliance with MHPAEA and this would include any changes to those benefits. The Department did not make any changes in response to this comment.

<u>Comment</u>: One commenter suggested the Department amend section 98-4.4(c) of the regulation to require that the MCO adopt internal rules requiring the sharing of information both within the organization and with any other parties engaged in benefit management services, such as entities performing utilization review activities on behalf of the MCO.

Response: An MCO is ultimately responsible for ensuring that it has a parity compliance program and that it is in compliance with MHPAEA, regardless of whether it contracts with any other parties engaged in benefit management services. Therefore, the Department does not feel it is necessary for the regulation to require an MCO to adopt internal rules requiring the sharing of information and the Department did not make any changes in response to this comment.

<u>Comment</u>: One commenter suggested that the Department amend section 98-4.4(d) of the regulation to require that the MCO's chief executive officer (CEO) sign the annual written certification to the Commissioner of Health specifying that the MCO meets the Parity Compliance Program requirements.

Response: The proposed regulation already requires that the annual certification be signed by the CEO or the individual responsible for assessing, monitoring, and managing the compliance program attesting to the best of his or her knowledge and belief that the information contained therein is true and that a copy of this certification has been provided to the MCO's board of directors or other governing body, or the appropriate committee thereof. Thus, the Department did not make any changes in response to this comment.

<u>Comment</u>: One commenter urged the Department to make clear that mental health benefits and substance use disorder benefits must each, independent of one another, comply with MHPAEA because MCOs should not have the false impression that they can lump mental health and substance use disorder together when conducting their benefit analyses.

Response: The Department believes that the proposed regulation is clear that MCOs must comply with MHPAEA as it relates to both mental health benefits and substance use disorder benefits. The preamble to the regulation specifically provides that the purpose of the regulation is to establish mental health and substance use disorder parity compliance program requirements to ensure that MCOs are providing comparable coverage for benefits to treat mental health and substance use disorder as required under both state and federal law. As a result, the Department did not make any changes in response to this comment.

Comment: One commenter expressed concern that the December 31, 2021 effective date for compliance set forth in the proposed regulation will allow noncompliance for too long and that the Department should amend the regulation to require MCOs to attest to compliance earlier, such as requiring attestation of compliance as part of an MCO's rate and form submission. In contrast, another commenter expressed concern that the effective date is overly aggressive and urged the Department to push back the effective date to December 31, 2022, as it will take time for MCO to assemble compliance teams with appropriate expertise and to develop and implement the required revised compliance program.

Response: In choosing an effective date, the Department must balance enrollee protections against the practical considerations related to operationalizing the requirements of the Parity Compliance Program. The December 31, 2021 effective date is a recognition that MCOs will need time to develop a Parity Compliance Program that complies with the regulation.

However, notwithstanding the regulation, MCOs currently must comply with MHPAEA. As a result, the Department did not make any changes in response to this comment.

<u>Comment</u>: One commenter suggested that the regulation should permit MCOs to designate more than one individual to assume the responsibility for assessing parity compliance.

Response: While the Department recognizes the need for more than one person to assist in the oversight of the Parity Compliance Program, the Department believes that one individual should oversee the entire Parity Compliance Program to ensure maximum responsibility, transparency, and accountability. Thus, the Department did not make any changes in response to this comment.

<u>Comment</u>: One commenter requested clarity regarding the language in section 98-4.4(a)(2)(i) of the regulation because the commenter thinks it is unclear as to what an MCO would do to define a benefit classification since existing law and regulations define the classifications.

Response: The Department is unclear what the commenter means. Section 98-4.4(a)(2)(i) references "a system for assigning each benefit to the defined benefit classifications as required by MHPAEA." The Department understands that existing law and regulations define the benefit classifications and believes the language in this section clearly reflects its intent to have a system in place that ensures the appropriate or correct designation of benefits. Per the language above, the MCO would not be defining the benefit classification but instead would be appropriately assigning each benefit to the defined benefit classification. The Department believes the commenter may have misinterpreted the language and therefore did not make any changes in light of this comment.

<u>Comment</u>: One commenter requested that the list of specific NQTL elements set forth in section 98-4.4(a)(4) of the regulation be replaced with a statement that the Parity Compliance Program be adequate to ensure parity compliance. The commenter's rationale was that the list is arbitrary and incomplete.

Response: The Department believes including the requirements set forth in section 98-4.4(a)(4)(i)-(ix) is essential to furthering the objective of mental health and substance use disorder parity compliance. The list is illustrative, not exhaustive. It was the Department's intent to include what it deemed to be the most significant minimum standards for assessing ongoing parity compliance. For these reasons, the Department did not make any changes in response to this comment.

Comment: One commenter requested that the Department revise or delete section 98-4.4(a)(4)(i) because a statistically valid sampling of denials is not indicative of whether determinations were consistent with approved clinical review criteria. The commenter further explained that the state has established greater limits on prior and concurrent utilization management for behavioral health then medical benefits, which may result in increased use of retrospective reviews for behavioral health by necessity. The commenter requested that the regulation recognize this and provide that these factors will be taken into account when evaluating MCO parity compliance.

Response: The Department acknowledges the commenter's concerns and notes that in the aforementioned scenarios, these factors will be considered. However, it is unclear whether revising the proposed regulation to include this level of granularity would be beneficial. As a result, the Department did not make any changes in response to this comment.

<u>Comment</u>: One commenter objected to the inclusion of section 98-4.4(a)(4)(i), which would require MCOs to "review the comparability of coverage within each benefit classification for mental health and substance use disorder benefits" because federal parity laws do not require a comparable continuum of services.

Response: The Department reviewed the language of the proposed regulation against the requirements of federal parity laws and regulations. While the proposed regulation provides more detail than federal parity laws and regulations, the proposed regulation is consistent with the objectives of MHPAEA and 45 C.F.R. Parts 146 and 147. Therefore, the Department did not make any changes in response to this comment.

Comment: One commenter suggested that the Department revise section 98-4.4(a)(4)(i) to clarify that the percentage of services provided by out-of-network providers for mental health and substance use disorder benefits where no in-network provider is available is a monitoring strategy and not a compliance issue. The commenter cited several reasons why the obligation to track cases where services are accessed on an out-of-network basis because no in-network option was available is burdensome and unpredictable and susceptible to being skewed by many factors.

Response: The Department appreciates the potential complications associated with gathering these types of data and is aware of the possibility of varying outcomes in certain instances. However, the Department believes this is an important metric for assessing parity compliance related to provider network standards and reimbursement rates. Thus, the Department did not make any changes in response to this comment.

<u>Comment</u>: One commenter requested that the Department revise section 98-4.4(a)(4)(iv) to separately address credentialing policies and network adequacy.

Response: The Department believes the language of the proposed regulation in its current form addresses network adequacy and credentialing separately under section 98-4.4(a)(4)(iv) and (5). As a result, the Department did not make any changes to the regulation in response to this comment.

Comment: One commenter noted that the language in section 98-4.4(a)(4)(v) of the regulation, which states that the "review of the average length of time to negotiate provider agreements and negotiated reimbursement rates with network providers and methods for the determination of usual, customary, and reasonable charges," is an example of an outcome measure not highly correlated with parity compliance and requested the deletion of this language.

Response: While the Department acknowledges that this metric may be influenced by factors outside of an MCO's control, the Department believes these are important metrics for parity compliance related to provider network standards and reimbursement rates. Therefore, the Department did not make any changes in response to this comment.

<u>Comment</u>: One commenter requested that the review of MCO policies for automatic or systematic non-payment or down-coding of current procedure terminology (CPT) codes not be applied in instances when an MCO is following generally accepted rules.

Response: The Department notes that section 98-4.4(a)(4)(vi) requires that the systematic payment or down-coding of CPT codes used for mental health and substance use disorder benefits be comparable to and applied no more stringently than it is to medical or surgical benefits. A generally accepted rule to apply these standards in a manner that is not comparable would not exempt an MCO from this requirement. Therefore, the Department did not make changes in response to this comment.

Comment: One commenter requested clarification regarding what is meant by "all mental health and substance use disorder medications" as used in section 98-4.4(a)(4)(vi) of the regulation. The commenter also stated that the requirement to provide a demonstration that considers factors other than cost, including latency periods, in determining whether to apply a step therapy or prior authorization requirement goes beyond the scope of mental health parity requirements and should be deleted. Finally, the commenter requested clarification on the distinction between step therapy requirements referenced in section 98-4.4(a)(4)(vii) of the regulation and fail first requirements referenced in section 98-4.4(a)(4)(viii) of the regulation.

Response: The Department is unsure what the commenter means when the commenter asks for clarification regarding "all mental health and substance use disorder medications." Based on the language of the proposed regulation, "all mental health and substance use disorder medications" would include all medications used for the treatment of mental health conditions and substance use disorder that are subject to NQTLs. Regarding the reference to cost and latency periods, the Department believes the commenter misread the regulation, as the regulation merely lists those as examples of factors MCOs sometimes rely on in determining whether to impose an NQTL. It is consistent with MHPAEA to require that, whatever factors are used, such factors are comparable to and applied no more stringently than the factors used to determine whether to impose an NQTL on a medical or surgical benefit. Regarding the distinction between step therapy in section 98-4.4(a)(4)(vii) and fail first requirements referenced in section 98-4.4(a)(4)(viii), the Department notes that section 98-4.4(a)(4)(vii) relates to prescription drugs specifically, while section 98-4.4(a)(4)(viii) relates to mental health and substance use disorder benefits generally. As a result, the Department did not make any changes in light of these comments.

<u>Comment</u>: One commenter recommended that the Department remove "actuarial" from section 98-4.4(a)(5) of the regulation because federal regulators have indicated that actuarial certification is not a requirement of quantitative limit for financial requirement testing.

Response: As a part of the proposed regulation's minimum standards for parity compliance, section 98-4.4(a)(5) includes "a process for the actuarial certification, in compliance with actuarial standards of practice, of the data used for, and the outcome of, the analyses of the financial requirements and quantitative treatment limitations applicable to mental health and substance use disorder benefits to ensure that they are no more restrictive than the predominant financial requirements and quantitative treatment limitations applied to substantially all the medical and surgical benefits." The Department has reviewed this recommendation and believes that requiring an actuarial certification is both warranted in this instance and necessary to ensure the soundness of the data used for parity analysis. The Department did not make any changes in response to this comment.

<u>Comment</u>: With respect to improper practices, one commenter requested that the Department define the "level of documentation" referenced in section 98-4.4(b)(1)(i) of the regulation.

Response: The Department did not define or qualify "level of documentation" to allow for a broad interpretation as applicable. For instance, this could refer to the amount or type of documentation. As a result, the Department did not make any changes in response to this comment.

<u>Comment</u>: One commenter requested that the Department define the methodology for calculating the percentage of benefits in section 98-4.4(b)(1)(ii).

Response: Section 98-4.4(b)(1)(ii) states that the following shall be considered an improper practice related to mental health and substance use disorder benefits: "requiring preauthorization, concurrent, or retrospective utilization review for a higher percentage of mental health or substance use disorder benefits in the absence of defined clinical or quality triggers, as compared to medical or surgical benefits." The Department believes defining the methodology for this calculation is unnecessary as this requires a basic comparison between the percentage of mental health and substance use disorder benefits with preauthorization, concurrent, or retrospective utilization review requirements as compared to medical and surgical benefits with preauthorization, concurrent, or retrospective utilization review requirements. Therefore, the Department did not make any changes in response to this comment.

<u>Comment</u>: With respect to section 98-4.4(b)(1)(iii) of the regulation, one commenter raised a concern that the payment rate provisions do not reflect local market factors or differences in intensity of the service delivery that warrant variations in reimbursement. For example, inpatient treatment for mental health conditions and substance use disorder is commonly less intensive and less costly than medical or surgical hospitalization.

Response: Section 98-4.4(b)(1)(iii) states that the following shall be considered an improper practice related to mental health and substance use disorder benefits: "implementing a methodology for developing and applying provider reimbursement rates for mental health or substance use disorder benefits that is not comparable to or is applied more stringently than the methodology for developing and applying provider reimbursement rates for medical or surgical benefits." The Department notes that the focus of this improper practice is the methodology for developing and applying provider reimbursement rates and not the actual reimbursement rates. Such methodologies may include consideration of various factors, including local market factors

and cost, as long as they are applied comparably and no more stringently to mental health and substance use disorder services than medical or surgical services. Thus, the Department did not make any changes in response to this comment.

<u>Comment</u>: One commenter requested that the Department change the maximum allowed 60-day time period after discovery to remediate and report improper practices to a 30-day period. In contrast, another commenter noted that remediation may take longer than 60 days given the wide variety in NQTLs and suggested removing the 60-day reference and replacing it with "as soon as commercially reasonable."

Response: The Department understands that MCOs may need more than 30 days to remediate certain improper practices and believes a 60-day timeframe is most appropriate. Further, replacing a specific timeframe with a "commercial reasonableness" standard of an indefinite duration presents enforcement issues and the potential for undue delay and enrollee harm. Thus, the Department did not make any changes in response to these comments.

<u>Comment</u>: One commenter requested that the Department revise Section 98-4.4(c) of the regulation to clarify what activities are included in the term "benefit management services."

Response: Section 98-4.4(c) states that "an MCO shall be responsible for and coordinate parity compliance monitoring activities with any agents and other representatives providing benefit management services or performing utilization review activities on behalf of the MCO." The Department understands that an MCO may have several different vendors and contractors managing its benefits and the term "benefit management services" is used broadly here to be inclusive of any and all such third-party vendors and contractors. The Department does not believe further clarification is necessary in this instance. The Department did not make any changes to the regulation in response to this comment.

<u>Comment</u>: One commenter requested clarification on what period the initial certification is intended to cover under section 98-4.4(d) of the proposed regulation.

Response: The initial certification requires that the MCO have a compliant Parity Compliance Program as of December 31, 2021. Each year thereafter the MCO will certify that it continues to maintain a compliant Parity Compliance Program.

<u>Comment</u>: With regard to the certification form prescribed by the Commissioner, one commenter suggested that the Department either convene a work group to provide input into the form or allow stakeholders to review and comment on the form when developed.

Response: The Department will consider this suggestion. Since this comment did not suggest any changes to the regulation, the Department did not make any.

<u>Comment</u>: One commenter suggested that the Department revise the definition of benefit classification in section 98-4.3(a) to include "and/or medication administration-dispensing visits" to ensure that office visits to opioid and medication assisted treatment providers are distinguishable from other office visits.

Response: MHPAEA defines the benefit classifications, thus the addition to section 98-4.3(a) cannot be made. The Department did not make any changes to the regulation in response to this comment.

<u>Comment</u>: One commenter suggested the Department revise section 98-4.4(a)(4)(iii) to add that the review will include corresponding percentage of services provided by in-network mental health and substance use disorder providers for each OMH/OASAS certification, where no out-of-network benefits were utilized.

Response: The Department feels that the section, as written, is inclusive of all mental health and substance use disorder providers. Thus, the Department did not make any changes to the regulation in response to this comment.

<u>Comment</u>: One commenter suggested the Department revise section 98-4.4(b)(1)(4) by adding language to address claim edits or system configurations that provide higher rates of claims denied.

Response: Section 98-4.4(b)(1)(4) addresses this issue by looking at higher rates of approval for medical and surgical benefits. The Department did not make any changes to the regulation in response to this comment.

<u>Comment</u>: One commenter suggested that since state law prohibits the use of preauthorization for many instances of substance use disorder treatment that the references to "preauthorization" be deleted or the statement "where allowed by law" be added.

Response: While the Department understands the concern regarding the use of the word preauthorization in sections that include substance disorder use treatment, the three instances where the term is used do not imply that preauthorization is allowed contrary to state law. The Department did not make any changes based on this comment.